



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO-P-2022-0031]

Extension of the Cancer Immunotherapy Pilot Program

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: On June 29, 2016, the United States Patent and Trademark Office (USPTO) implemented the Cancer Immunotherapy Pilot Program in support of the White House's National Cancer Moonshot initiative, which sought to accelerate cancer research. The program permits patent applications pertaining to cancer immunotherapy to be advanced out of turn for examination. To date, over 880 petitions requesting participation in the pilot program have been filed, and over 650 patents have been granted under the program. In view of the continued interest in the Cancer Immunotherapy Pilot Program, as well as the White House's reignition of the National Cancer Moonshot initiative, the USPTO is extending the program, with all parameters remaining the same, until January 31, 2023. The USPTO will also continue to evaluate whether to expand the scope of the pilot program and to what extent during this extension period.

DATES: *Pilot duration:* The Cancer Immunotherapy Pilot Program will continue to run until January 31, 2023. Therefore, petitions to make special under the Cancer Immunotherapy Pilot Program must be filed on or before January 31, 2023.

FOR FURTHER INFORMATION CONTACT: For questions regarding this pilot program in general, please contact Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, at 571-272-7711 or susy.tsang-foster@uspto.gov. For questions related to a particular petition, please contact Gary B. Nickol, Supervisory Patent Examiner, at 571-

272-0835 or gary.nickol@uspto.gov; or Brandon J. Fetterolf, Supervisory Patent Examiner, at 571-272-2919 or brandon.fetterolf@uspto.gov, both of Technology Center 1600.

SUPPLEMENTARY INFORMATION: On June 29, 2016, the USPTO published a notice for the implementation of the Cancer Immunotherapy Pilot Program. *See Cancer Immunotherapy Pilot Program*, 81 FR 42328 (Cancer Immunotherapy Notice). The pilot program was designed to support the global fight against cancer. The Cancer Immunotherapy Notice indicated that an applicant could have an application advanced out of turn (accorded special status) for examination without meeting all the current requirements of the accelerated examination program set forth in item VIII of section 708.02(a) of the Manual of Patent Examining Procedure (9th ed., rev. 10.2019, June 2020), if the application contained at least one claim to a method of treating a cancer using immunotherapy and the applicant met other requirements specified in the Cancer Immunotherapy Notice.

The Cancer Immunotherapy Notice established that the pilot program would run for 12 months, beginning on June 29, 2016. Over the course of the pilot program, the USPTO has extended it four times through notices published in the Federal Register. The most recent notice extended the program until September 30, 2022 and requested public comments on whether to expand the scope of pilot program and whether to extend it. *See Extension of the Cancer Immunotherapy Pilot Program and Request for Comments*, 87 FR 38714 (June 29, 2022) (Extension Notice). The Office received one written submission containing three comments from a law firm in response to the request for public comments in the Extension Notice. The Office appreciates the thoughtful comments. The submission is posted at <https://www.regulations.gov/document/PTO-P-2022-0019-0001/comment>. The USPTO is continuing to evaluate whether to expand the program and to what extent.

Various stakeholders from around the world—including independent inventors, universities, research institutions, hospitals, medical centers, government agencies, and large and small companies—have filed petitions to participate in the pilot program. To date, over 880 petitions requesting participation have been filed, and over 650 patents have been granted under the pilot program. In view of the continued interest in the pilot program, the USPTO is hereby extending it through January 31, 2023. The extension will enable the program to continue without lapse as the USPTO continues its ongoing evaluation of whether to expand the program and to what extent. The requirements of the pilot program will not be modified at this time.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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